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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,038	08/09/2001	Hisatomi Ito	NANP110US	4720
23623	7590	11/17/2005	EXAMINER	
AMIN & TUROCY, LLP 1900 EAST 9TH STREET, NATIONAL CITY CENTER 24TH FLOOR, CLEVELAND, OH 44114			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/927,038		ITO ET AL.	
	Examiner		Art Unit	
	Cybille Delacroix-Muirheid		1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,9-12,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,9-12,14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

1. Claims 4, 5, 9-12, 14, 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Guthrie et al., 6,251,400 B1.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment(s)

The following is responsive to applicant's amendment received Aug. 29, 2005.

Claims 1-3, 6-8, 13 are cancelled. No new claims are added. Claims 4-5, 9-12, 14-15 are currently pending.

Applicant's arguments traversing the previous rejection of claims 4, 5, 9-12, 14, 15 under 35 USC 102(e) over Guthrie et al., 6,251,400, set forth in paragraph 1 of the office action mailed June 3, 2005, have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed June 3, 2005 with the following additional comment.

Applicant argues that nothing in Guthrie suggests impliedly or inherently the claimed method for extending neuritis and treating encephalic ischemia. To establish inherency the missing descriptive matter must necessarily result from that which is described in the prior art. Guthrie discloses that limonoids, flavonoids tocotrienols and/or tamoxifen can be used for treating neoplastic diseases by showing that those compounds inhibit tumor cell proliferation. Guthrie teaches that tangeretin and nobiletin effectively inhibit tumor cell growth by 50% at the low concentration. Guthrie rather teaches away from the claimed method for treating encephalic ischemia by extending neuritis. Therefore the examiner has not provided a sufficient basis in fact

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and/or technical reasoning to reasonably support the inherency assertion based on the teachings of Guthrie.

Said arguments have been considered but are not found to be persuasive.

The examiner appreciates that the Guthrie reference does not disclose applicant's claimed methods *in haec verba*. However, Guthrie's disclosure fully meets the terms of the claimed methods. Please note that applicant's claims require the administration of the extract composition containing the polyalkoxyflavonoid of formula (1) to "a subject", not just subjects in need of extension of neurites or treatment of encephalic ischemia. Any individual being treated with the claimed composition falls within the scope of the claimed methods. Furthermore, Guthrie teaches administration of an identical composition containing an extract from tangerines (nobiletin or tangeretin). Therefore, extension of neuritis and treatment of encephalic ischemia would be inherent. Claims 11 and 14 remain anticipated by Guthrie because contact with neurocytes is inherent in the methods of Guthrie since contact would also be achieved subsequent to the administration of the citrus compounds to the subject.

Moreover, applicant's remarks concerning Guthrie's teaching of tangeretin and nobiletin's tumor inhibiting properties are noted. However, Guthrie does not teach away from the claimed methods since tumors consist of abnormal cells, which are distinct from the nerve cells of the instant claims. Finally, the examiner notes that the claims, as amended, recite "consisting essentially of" language. According to MPEP 2111.03, "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). If an applicant contends that

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additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). In this case, applicant has not presented arguments as to how the additional materials in Guthrie materially affect the characteristics of the claimed invention.

The rejection is respectfully maintained.

Conclusion

Claims 4-5, 9-12, 14-15 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Nov. 12, 2005



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